

Data Evaluation Report on the acute toxicity of aldicarb to Bluegill Sunfish (*Lepomis macrochirus*)

PMRA Submission Number {.....}

EPA MRID Number 45592113

Data Requirement:

PMRA DATA CODE	{.....}
EPA DP Barcode	Not provided
OECD Data Point	
EPA MRID	45592113
EPA Guideline	72-1(a)

Test material: Aldicarb **Purity:** 99.5%
Common name: Aldicarb
Chemical name: IUPAC: 2-Methyl-2-(methylthio)propionaldehyde-O-methylcarbamoyloxime
CAS name: 2-Methyl-2-(methylthio)-propanal O-[(methylamino)carbonyl]oxime
CAS No.: 116-06-3
Synonyms: RPA 021149, RPA024742, RPA030424, RPA590013, and LS885108

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation

Signature: Rebecca Bryan
Date: 8/28/02

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OPP/EFED/ERB - II

Date: 9/9/02

Secondary Reviewer(s):
{EPA/OECD/PMRA}

Date:

Reference/Submission No.

Company Code:

Active Code:

EPA PC Code: 098301

Date Evaluation Completed:

CITATION: Odin-Feurtet, M. 1999. Aldicarb - Acute Toxicity (96-Hour) to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions. Unpublished study performed by Rhone-Poulenc Agro, Sophia Antipolis, France. Laboratory Study No. 99331. Study submitted by Rhone-Poulenc Agro France, Lyon, France. Study initiated August 5, 1999 and completed October 15, 1999.



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EXECUTIVE SUMMARY:

In a 96-hour acute toxicity study, Bluegill Sunfish (*Lepomis macrochirus*) were exposed to aldicarb at nominal concentrations of 0 (negative and solvent controls), 31.3, 62.5, 125, 250, and 500 $\mu\text{g/L}$ under static conditions. The mean-measured concentrations for the 31.3 and 500 $\mu\text{g/L}$ treatment groups were 39 and 577 $\mu\text{g/L}$, respectively. Following 96 hours of treatment, 10, 50, 100, and 100% mortality was observed in the 62.5, 125, 250, and 500 $\mu\text{g/L}$ (nominal) treatment groups, respectively. No mortality was observed in the dilution water control, solvent control, or 31.3 $\mu\text{g/L}$ treatment groups during the study. The LC_{50} (with 95% C.I.) was 114.8 (85.9 to 153.8) $\mu\text{g/L}$, which categorizes aldicarb as highly toxic to juvenile Bluegill sunfish (*Lepomis macrochirus*) on an acute toxicity basis. Erratic swimming, moribund appearance, and/or lethargy were observed in surviving fish from the ≥ 250 $\mu\text{g/L}$ groups at 0-4 hours, in surviving fish from the ≥ 125 $\mu\text{g/L}$ groups at 24 hours, and in surviving fish from the ≥ 62.5 $\mu\text{g/L}$ groups at 48 through 96 hours. The NOEC and LOEC observed for both mortality and sublethal effects were 31.3 and 62.5 $\mu\text{g/L}$, respectively.

Since the mean fish weight of 0.21 g, determined from ten "representative" fish at test termination, was significantly less than the required initial weight range of 0.5 to 5 g, and since analytical measurements were not determined for each test level, this study does not fulfill guideline requirements for an acute toxicity study with the bluegill [§72-1(a)] and is classified SUPPLEMENTAL.

Results Synopsis

Test Organism Size/Age (mean Weight or Length): 0.21 g (wet), 2.9 cm (mean of ten fish at study termination)

Test Type (Flow-through, Static, Static Renewal): Static

96-Hour

LC_{50} : 114.8 $\mu\text{g/L}$ 95% C.I.: 85.9-153.8 $\mu\text{g/L}$

Slope: 5.69 95% C.I.: 2.6-8.8

NOEC: 31.3 $\mu\text{g/L}$

LOEC: 62.5 $\mu\text{g/L}$

Endpoints affected: Mortality and sublethal effects (same conclusions)

I. MATERIALS AND METHODS

GUIDELINES FOLLOWED: The study protocol was based on procedures outlined in OECD Guideline No. 203 (1992) and the EEC Directive 92/69, Method C1 (1992). Deviations from U.S. EPA guideline §72-1 included:

1. Mean wet fish weight (0.21 g) was determined from the ten "representative" fish at study termination, and was significantly less than the recommended initial range of 0.5-5g.
2. Verification of the concentration of aldicarb in test solution was conducted at the low and high test levels only.
3. Test solutions were aerated during the definitive experiment.
4. The dilution water hardness was reported as 10-250 mg/L; EPA requires a hardness of 40-48 mg/L.

5. Dissolved oxygen was not provided in terms of percent saturation.
6. The total organic carbon content, particulate matter, metals, pesticides, and amount of chlorine in the dilution water were not specified.
7. The biomass loading rate was not reported.

These deviations do not affect the validity of the study. However, since terminal weights were significantly below the initial required weight range of 0.5-5 g, and since analytical verification of the test substance in solution was not determined at each concentration level, this study does not fulfill guideline requirements.

COMPLIANCE:

Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided. This study was conducted in compliance with GLP Regulations of the OECD (1997), EEC (1986), U.S. EPA (1989), and French Decree No. 98-1312 (1998) with the following exception: routine water and food contaminants screening analyses for pesticides, PCBs, heavy metals and other possible contaminants were not collected in accordance with GLP procedures.

A. MATERIALS:

1. Test Material

Aldicarb

Description:

White crystals

Lot No./Batch No. :

8KJ092

Purity:

99.5%

Stability of Compound

Under Test Conditions: The stability of the test substance in the dilution water during the course of the study was demonstrated by analytical determination at 0 and 96 hours. Results are presented in Table 2, p. 27.

OECD requires water solubility, stability in water and light, pK_a , P_{ow} , and vapor pressure of the test compound. OECD requirements were not reported.

Storage conditions of test chemicals: Stored dry at $<5^{\circ}\text{C}$.

2. Test organism:

Species: Bluegill Sunfish (*Lepomis macrochirus*)

Age at test initiation: Juvenile

Weight at study initiation: Not provided; the wet weight of ten representative fish measured at test termination averaged 0.21 g (range = 0.15-0.28 g)

Length at study initiation: Not provided; the length of ten representative fish measured at test termination averaged 2.9 cm (range = 2.7-3.0 cm)

Source: BIO International, Nantes, France.

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: No range-finding data were provided. Selection of aldicarb concentrations for the definitive study was based on available toxicity information.

b) Definitive Study:

Table 1. Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period:	≥ 12 days	<i>EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.</i>
Conditions (same as test or not):	Same as test	
Feeding:	Fed a commercial pellet trout food twice daily, except during the 24 hours prior to test initiation.	
Health: (any mortality observed)	0.8% mortality (2 fish).	
Duration of the test	96 hours	<i>EPA/OECD requires: 96 hour</i>
Test condition	Static	<i>EPA: Must provide reproducible supply of toxicant, with a consistent flow rate of 5-10 vol/24 hours, and meter systems calibrated before study and checked twice daily during test period</i>
static/flow through		
Type of dilution system - for flow through method	N/A	
Renewal rate for static renewal	N/A	
Aeration, if any	Test solutions were aerated during the test.	Aeration is not recommended.
		<i>EPA requires: no aeration; OECD permits aeration</i>

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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u>		
Material: (glass/stainless steel)	Glass vessels	
Size:	Not reported.	EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm
Fill volume:	20 L	Fill volume: 15-30 L of solution)
Source of dilution water:	Reconstituted water (composition details provided in Appendix 2, pp. 34-37)	
		EPA 1975; Soft reconstituted water or water from a natural source, not dechlorinated tap water; OECD permits dechlorinated tap water.
<u>Water parameters:</u>		
Hardness	10-250 mg CaCO ₃ /L	The water hardness and pH levels exceeded recommendations.
pH	7.2-7.6	Dissolved oxygen was not provided in terms of percent saturation.
Dissolved oxygen	7.9-8.4 mg/L	
Total Organic Carbon	Not detected	
Particulate Matter	Not detected	
Metals	Not detected	
Pesticides	Not detected	
Chlorine	Not reported	
Temperature	21.4-22.2°C	
Intervals of water quality measurements	DO, pH, and temperature were determined daily in each replicate aquarium. Temperature was also continuously monitored in one replicate aquarium. Hardness was determined at test initiation. Routine analysis for the presence of pesticides, PCBs, heavy metals, and other contaminants are conducted every six months (results in Appendix 2, pp. 34-37).	<p>Hardness and pH EPA requires hardness of 40-48 mg/L as CaCO₃ and pH of 7.2-7.6 OECD allows hardness of 10-250 mg/L as CaCO₃ and pH between 6 and 8.5.</p> <p>Dissolved Oxygen <u>Renewal:</u> ≥60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs <u>Flow-through:</u> ≥60% through out test. OECD requires at least 80% saturation value.</p> <p>Temperature EPA requires 12°C for rainbow trout and 17 or 22°C for bluegill. OECD requires range of 21 - 25°C for bluegill and 13-17°C for rainbow trout.</p> <p>EPA water quality Measured at beginning of test and every 48 hours</p>

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Parameter	Details	Remarks
		Criteria
<u>Concentration of test material:</u> nominal: measured:	0 (negative and solvent controls), 31.3, 62.5, 125, 250, and 500 $\mu\text{g/L}$ <20 (LOQ, negative and solvent controls), 39 (lowest treatment), and 577 $\mu\text{g/L}$ (highest treatment).	Analytical measurements were only conducted at the low (after 0 and 96 hours) and high (after 0 and 24 hours, due to 100% mortality) treatment levels. <i>EPA/OECD requires: Control and five treatment levels. Each conc. should be 60% of the next highest conc., and should be in a geometric series</i>
Solvent (type, percentage, if used)	Acetone, 0.05 mL/L	<i>EPA requires: Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow- through tests; OECD requires solvent , exceed 100 mg/L.</i>
<u>Number of fish/replicates:</u> negative control: solvent control: treated:	10 fish/replicate, one replicate 10 fish/replicate, one replicate 10 fish/replicate, one replicate/concentration	<i>EPA: $\geq 10/\text{concentration}$; OECD requires at least 7 fish/concentration</i>
Biomass loading rate	Not reported.	<i>Static: $\leq 0.8 \text{ g/L}$ at $\leq 17^\circ\text{C}$, $\leq 0.5 \text{ g/L}$ at $> 17^\circ\text{C}$; flow-through: $\leq 1 \text{ g/L/day}$; OECD requires maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through</i>
Lighting	16 hour light:8 hour dark photoperiod	<i>EPA requires: 16 hours light/8 hours dark; OECD requires 12 -16 hours photoperiod.</i>
Feeding	None	<i>EPA/OECD requires: No feeding during the study</i>

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Parameter	Details	Remarks
		Criteria
Recovery of chemical	97-118%	Based on procedural recoveries (Table 1, p. 26).
Level of Quantitation	20 µg/L	
Level of Detection	Not reported	
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	N/A	

2. Observations:**Table 2: Observations**

Criteria	Details	Remarks/Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and sublethal effects.	
Observation intervals	3, 24, 48, 72, and 96 hours of exposure	<i>EPA/OECD requires: minimally every 24 hours</i>
Were raw data included?	Yes	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION:**A. MORTALITY:**

Following 96 hours of treatment, 10, 50, 100, and 100% mortality was observed in the 62.5, 125, 250, and 500 µg/L (nominal) treatment groups, respectively. No mortality was observed in the dilution water control, solvent control, or 31.3 µg/L treatment groups during the study.

Table 3: Effect of Aldicarb on mortality of Bluegill Sunfish (*Lepomis macrochirus*).

Nominal Test Concentrations ($\mu\text{g/L}$) ¹	No. of fish at start of study	0-4 Hours		24 Hours		48 Hours		72-96 Hours	
		No Dead	% mortality	No Dead	% mortality	No. Dead	% mortality	No Dead	% mortality
Negative Control	10	0	0	0	0	0	0	0	0
Solvent Control	10	0	0	0	0	0	0	0	0
31.3	10	0	0	0	0	0	0	0	0
62.5	10	0	0	0	0	1	10	1	10
125	10	0	0	1	10	2	20	5	50
250	10	0	0	8	80	10	100	10	100
500	10	3	30	10	100	10	100	10	100
NOEC	31.3 $\mu\text{g/L}$								
LC ₅₀	115 $\mu\text{g/L}$ (95% C.I. = 86-154 $\mu\text{g/L}$)								
Positive control, if used mortality: LC ₅₀ :	N/A N/A								

¹ Nominal test concentrations are reported. Mean measured concentrations were not determined for all test concentrations.

B. NON-LETHAL TOXICITY ENDPOINTS:

Sublethal effects, including erratic swimming, moribund appearance, and/or lethargy, were observed in surviving fish from the $\geq 250 \mu\text{g/L}$ groups at 0-4 hours, in surviving fish from the $\geq 125 \mu\text{g/L}$ groups at 24 hours, and in surviving fish from the $\geq 62.5 \mu\text{g/L}$ groups at 48 through 96 hours.

Table 4. Sub-lethal effects of Aldicarb on Bluegill Sunfish (*Lepomis macrochirus*).

Nominal Test Concentrations ($\mu\text{g/L}$)	Observation Period				
	endpoint at 0-4 Hours	endpoint at 24 Hours	endpoint at 48 Hours	endpoint at 72 Hours	endpoint at 96 Hours
	% Affected ²				
Negative Control	None observed	None observed	None observed	None observed	None observed
Solvent Control	None observed	None observed	None observed	None observed	None observed
31.3	None observed	None observed	None observed	None observed	None observed
62.5	None observed	None observed	Erratic swimming; 33%	Erratic swimming, 22%	Erratic swimming, 11%
125	None observed	Erratic swimming; 67% Moribund, 22%	Erratic swimming; 88% Moribund, 12%	Erratic swimming; 100%	Erratic swimming; 80%, Lethargy, 20%
250	Erratic swimming; 70% Moribund, 30%	Moribund, 100%	---	---	---
500	Moribund, 100%	---	---	---	---
NOEC (sublethal)	31.3 $\mu\text{g/L}$				
LOEC (sublethal)	62.5 $\mu\text{g/L}$				
EC ₅₀	Not determined.				
Positive control, if used % sublethal effect; EC ₅₀ :	N/A				

¹ Nominal test concentrations are reported. Mean measured concentrations were not determined for all test concentrations.

² Percent affected reviewer-calculated from number affected \div number surviving at each interval.

--- 100% Mortality

C. REPORTED STATISTICS:

The LC₅₀ value was calculated according to Stephan (1977) using the probit method. The no-observed effect level was based on direct inspection of the data.

D. VERIFICATION OF STATISTICAL RESULTS:

The LC₅₀ value (with 95% C.I.) was estimated with the probit method via TOXANAL software. The NOEC and LOEC levels were visually determined, based on observed treatment-related mortality or sublethal effects.

96-Hour

LC₅₀: 114.8 µg/L

95% C.I.: 85.9-153.8 µg/L

Slope: 5.69

95% C.I.: 2.6-8.8

NOEC: 31.3 µg/L

LOEC: 62.5 µg/L

Endpoints affected: Mortality and sublethal effects (same conclusions)

E. STUDY DEFICIENCIES:

The mean fish weight of 0.21 g was determined from ten "representative" (not further specified) fish at study termination and was significantly less than the required initial weight range of 0.5-5 g. In addition, aldicarb concentrations were only analytically determined at the low and high treatment levels. As a result, this study does not fulfill guideline requirements for an acute toxicity study with the bluegill [§72-1(a)] and is classified SUPPLEMENTAL.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions are identical to those reported by the study authors.

Although the solutions were aerated during the definitive study, this did not appear to affect the test concentrations (Table 2, p. 27).

G. CONCLUSIONS:

This study is scientifically sound, but does not satisfy the guideline requirements for an acute toxicity study with freshwater fish (§72-1) because the mean weight of the organisms, obtained from ten "representative" fish at study termination, was 0.21 g, which is significantly less than the required initial weight range of 0.5 to 5 g. In addition, mean measured concentrations were determined for only the low and high test levels. This study provides useful information, and is classified SUPPLEMENTAL. Based on the results of this study, aldicarb is categorized as highly toxic to juvenile Bluegill sunfish (*Lepomis macrochirus*) on an acute toxicity basis.

96-Hour

LC₅₀: 114.8 µg/L

95% C.I.: 85.9-153.8 µg/L

Slope: 5.69

95% C.I.: 2.6-8.8

NOEC: 31.3 µg/L

LOEC: 62.5 µg/L

Endpoints affected: Mortality and sublethal effects (same conclusions)

III. REFERENCES:

E.E.C. 1992. Annex to Commission Directive 92/69/E.E.C. of 31 July 1992. Official Journal Publication No. L383A - Part C: Methods for the determination of ecotoxicology C.1. "Acute toxicity for fish."

O.E.C.D. 1992. Guidelines for testing of chemicals. Section C: Effects on Biotic Systems: 203 - "Fish, acute toxicity test" (adopted: 17 July, 1992).

Lafay, G., and J.P. Tassel. 1999. Aldicarb: Determination by Gas Chromatography analysis in freshwater for

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ecotoxicology: ANL/208-99E, Rhone-Poulenc Agro, Sophia Antipolis Research Centre, France.

Stephan, C.E. 1977. Methods for calculating on LC_{50} in: Aquatic toxicology and Hazard evaluation, ASTM STP 634, Mayer, F.L. and Hamelink, J.L. (eds) pp. 65-84.

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APPENDIX 1. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

LC₅₀

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 125

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.1143083	110.8235	78.25151	152.1515

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.2970852	1	.8603098

SLOPE = 5.692419

95 PERCENT CONFIDENCE LIMITS = 2.589736 AND 8.795102

LC50 = 114.8553

95 PERCENT CONFIDENCE LIMITS = 85.86798 AND 153.7933

LC10 = 68.71431

95 PERCENT CONFIDENCE LIMITS = 33.80544 AND 90.57056